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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/147,346 03/01/99 YARKONI

S 1268-073

EXAMINER

HM22/0313

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ART UNIT

PAPER NUMBER

1642

DATE MAILED:

03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Best Available Copy

Office Action Summary

Application No.
09/147,346

Applicant(s)
Yarkoni et al

Examiner
Larry R. Helms Ph.D.

Group Art Unit
1642



☒ Responsive to communication(s) filed on 18 Jan 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-7 and 9-28 is/are pending in the application.

Of the above, claim(s) 11-20 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7, 9, 10, and 21-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

DETAILED ACTION

1. Claims 1-7 and 9-28 are pending.

Claims 1-7, 9-10, 22 have been amended and Claims 23-28 have been added in the amendments of 9/13/00 and 1/18/01.

2. Claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

3. Claims 1-7, 9-10, and 21-28 are under examination.

4. The text of those sections of title 35, USC Code not included on the Office Action can be found in a prior Office Action.

Drawings

5. The Examiner acknowledges the submission of new drawings, however, no new drawings were attached to the amendment of 9/13/00 or 1/18/01.

Appropriate correction is required.

Rejections Withdrawn

6. The rejection of Claims 1-7, 9-10, 21, and 22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Art Unit: 1642

applicant regards as the invention is withdrawn in view of the amendments to the claims and arguments.

7. The rejection of Claims 1-7, 9-10, 21, 22 under 35 U.S.C. 112, first paragraph is withdrawn.

Response to Arguments

8. The rejection of Claims 1-2, and 7 under 35 U.S.C. 102(b) as being anticipated by Nett et al (WO 90/09799, published 9/7/90, IDS paper # 10) is maintained.

The responses filed 9/13/00 and 1/18/01 have been carefully considered but is deemed not to be persuasive. The response states "The instant claimed product chimeras are different biological molecules as compared to the molecules disclosed in the references because they have been made in a different way and because they start from different starting molecules" (see page 21 of response of 9/13/00). In response to this argument, as stated previously

"The method in which the targeted fused chimeric toxins were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966

Art Unit: 1642

(Fed. Cir. 1985). See also MPEP 2113.” and the rejected claims do not state any starting material and as such the prior art product reads on the claims.

9. The rejection of Claims 1, 2, and 7 under 35 U.S.C. 102(b) as being anticipated by Lombardo et al (WO 93/15751, published 8/19/93, IDS paper # 10) is maintained for reasons stated above.

10. The rejection of Claims 1, 2, and 7 under 35 U.S.C. 102(b) as being anticipated by Rusiecki et al (IDS paper # 10) is maintained for reasons stated above.

11. The rejection of Claims 3, 4, 21 and newly added claim 27 under 35 U.S.C. 103(a) as being unpatentable over Nett et al and further in view of Chaudhary et al (The Journal of Biological Chemistry 265:16306-16310, 1990) is maintained.

The responses filed 9/13/00 and 1/18/01 have been carefully considered but is deemed not to be persuasive. The response states “The claims are directed to a GnRH analog ligated to a mutated toxin. That is simply not disclosed in the art.” (See page 23 of response). In response to this argument. The response does not address any of the references and the rejection is based on 35 U.S.C. 103(a) not 102. It is reiterated that it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a targeted

Art Unit: 1642

fused chimeric toxin comprising (1) GnRH as taught by Nett et al and (2) a mutated form of PE or PE40 which contains domains II and III of PE as taught by Chaudhary et al.

12. The rejection of Claims 1-7, 9-10, 21, 22, and newly added claims 23-28 under 35 U.S.C. 103(a) as being unpatentable over Nett et al, and further in view of Chaudhary et al {a} (Nature 339:394-397, 1989) and Chaudhary et al {b} (Proc. Natl. Acad. Sci. USA 84:4538-4542, 1987) is maintained.

The responses filed 9/13/00 and 1/18/01 have been carefully considered but is deemed not to be persuasive. The response did not addresses this rejection. In addition, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat the recited adenocarcinomas in claims 23-28 because it was known in the art that GnRH analogs have been demonstrated in several carcinomas of breast, prostate, pancreatic, endometrial, and ovarian (see page 2 of specification).

Conclusions

13. No Claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1642

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official

Application/Control Number: 09147346

Page 7

Art Unit: 1642

Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879


SHEELA HUFF
PRIMARY EXAMINER